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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/598,816

12/14/2006

Tomaz Mesar

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1649

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7590

10/11/2011

Lek (Slovenia) - LUEDEKA, NEELY & GRAHAM, P.C.

P.O. BOX 1871

Knoxville, TN 37901

EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT

PAPER NUMBER

1624

MAIL DATE

DELIVERY MODE

10/11/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/598,816	Applicant(s) MESAR ET AL.	
	Examiner BRENDA COLEMAN	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1-6,22,24,26,27,35 and 36 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1-6,22,24,26,27,35 and 36 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/1/2011</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Claims 1-6, 22, 24, 26, 27, 35 and 36 are pending in the application.

This action is in response to applicants' amendment filed April 1, 2011. Claims 1-4, 6, 22, 24, 35 and 36 have been amended.

Response to Amendment

Applicant's amendments filed April 1, 2011 have been fully considered with the following effect:

1. The applicants' amendments and arguments are sufficient to overcome the 35 U.S.C. § 102, anticipation rejection labeled paragraph 6) in the last office action, which is hereby **withdrawn**.
2. The applicants' amendments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejections labeled paragraph 7a), b), c), d), e), f), g), h), i), j), k), l) and m) in the last office action, which are hereby **withdrawn**.

In view of the amendment dated April 1, 2011, the following new grounds of rejection apply:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-6, 22, 24, 26, 27, 35 and 36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The following reasons apply:

- a. The amendment to claim 1 where step iii) includes contacting the adjusted pH “**aqueous** solution” is not described in the specification with respect to the purification of olanzapine;
- b. The amendment to claim 22 where step c) is to **transforming** the olanzapine acid addition salt to olanzapine, wherein the **transformation** comprises is not described in the specification with respect to the preparation of olanzapine;
- c. The amendment to claim 22 where step i) is to dissolving the acid addition salt of olanzapine in water to form an “**aqueous** solution” is not described in the specification with respect to the preparation of olanzapine;

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- d. The amendment to claim 22 where step ii) where adjusting the pH of the **"aqueous"** solution" is not described in the specification with respect to the preparation of olanzapine;
- e. The amendment to claim 22 where step iii) is to contacting the adjusted pH **"aqueous"** solution" with an organic solvent to form a water phase and an organic phase is not described in the specification with respect to the preparation of olanzapine;
- f. The amendment to claim 22 wherein the olanzapine crystals include less than 0.5% of piperazine 1,4-bis-4-yl-(2-methyl)-10H-thieno-[2,3-b][1,5]benzodiazepine is not described in the specification with respect to the preparation of olanzapine from desmethyloanzapine;
- g. The amendment to claim 24 where step b) is to diluting the reaction mixture with water and **acidifying the mixture, as necessary**, with and acid is not described in the specification with respect to the preparation of olanzapine;
- h. The amendment to claim 24 where step c) is to adding a chlorinated organic solvent to the diluted reaction mixture to induce formation of **separate acidic** water and organic solvent phases..... is not described in the specification with respect to the preparation of olanzapine;
- i. The amendment to claim 24 where step e) is to **neutralizing** the water phase and extracting olanzapine is not describe in the specification with respect to the preparation of olanzapine; and

j. The amendment to claim 24 where step j) is to **transforming** the olanzapine acid addition salt to olanzapine is not described in the specification with respect to the preparation of olanzapine in the form of an acid addition salt. Applicant is required to cancel the new matter in the reply to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRENDA COLEMAN whose telephone number is (571)272-0665. The examiner can normally be reached on 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brenda L. Coleman/
Primary Examiner, Art Unit 1624